Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of two methods of group cognitive- behavioral therapy and group cognitive hypnotism on Degree of depression in girl students with premenstrual syndrome.

Protocol summary

Study aim

1-comparison of depression score before and after intervention in cognitive-behavioral group therapy in female students with premenstrual syndrome 2-comparison of depression scores before and after cognitive hypnosis intervention in female students with premenstrual syndrome 3- comparison of depression score in two cognitive-behavioral therapy groups and cognitive hypnosis in female students with premenstrual syndrome

Design

community-based and pragmatic control group, with parallel groups, blinded and randomized.

Settings and conduct

The aim of this study was to compare the effects of two methods of cognitive-behavioral group therapy and group cognitive hypnosis on depression in female students in 2018 in Islamic Azad University. The type of research is experimental . The study groups consisted of two experimental groups and one control group, who were not aware of the inclusion of one-way blind in intervention groups and only participated in a study to study the premenstrual syndrome.

Participants/Inclusion and exclusion criteria

Entering the study include being a student in one of the psychology courses, ages 18 to 50, the absence of mental disorders, including depression and PMS in the family, and the lack of drug use, and the exit criterion is the existence of a negative Spigel test for hypnosis.

Intervention groups

The first test group (cognitive-behavioral group therapy) The second test group (group of cognitive hypnosis treatment) The control group(non intervention)

Main outcome variables

Comparison of the Effect of Two Psychological Therapies on depression; The Effect of Two Psychological Therapies on depression in Students

General information

Reason for update

Acronym

PMS

IRCT registration information

IRCT registration number: **IRCT2016090228931N1**
Registration date: **2016-09-02, 1395/06/12**
Registration timing: **prospective**

Last update: **2018-04-29, 1397/02/09**
Update count: **1**

Registration date

2016-09-02, 1395/06/12

Registrant information

Name

Leila Moghtader

Name of organization / entity

Azad University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Rasht Azad University of Medical Sciences

Expected recruitment start date

2018-05-21, 1397/02/31

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of two methods of group cognitive- behavioral therapy and group cognitive hypnotism on Degree of depression in girl students with premenstrual syndrome.

Public title
Comparison of group cognitive- behavioral therapy and group cognitive hypnotism on Degree of depression in girl students.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Being a student in one of the psychology courses aged 18 to 50 years lack of medication
Exclusion criteria:
negative spiegel test for hypnosis
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In this research, simple randomization method will be used. In this way, people in the test and control groups or lottery will be selected and will be replaced by lottery in these groups. Accident Unit: Individual Randomization Tool: Draw a random numbered table Participants will not be aware of the status of the target group until the completion of the study.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants will not be aware of the status of the target group until the completion of the study.
Placebo
Not used
Assignment
Parallel
Other design features
After sampling, two experimental groups and one control group will be separat by lottery

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Rasht University of Medical Sciences
Street address
Rasht, Pole Taleshan, Azad University
City
Rasht
Province
Guilan
Postal code
4154974416
Approval date
2016-08-10, 1395/05/20
Ethics committee reference number
IR.GUMS.REC.1396.534

Health conditions studied

1

Description of health condition studied
Premenstrual Syndrome
ICD-10 code
F99
ICD-10 code description
Mental disorder, not otherwise specified

Primary outcomes

1

Description
Depression
Timepoint
Before and after the intervention
Method of measurement
Beck Depression Inventory

Secondary outcomes

empty

Intervention groups

1

Description
The first experimental group: eight 2-hour sessions of cognitive behavior therapy
Category
Behavior

2

Description
The first experimental group: eight 2-hour sessions of Cognitive Hypnotherapy

Category
Behavior

3

Description
No action
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Holistic Nursing Research Center
Full name of responsible person
Sedigheh Pakseresht
Street address
Rasht, belt martyr Beheshti, Faculty of Nursing and Midwifery
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Gilan University of Medical Sciences
Full name of responsible person
Sedigheh Pakseresht
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Rasht, belt martyr Beheshti, Faculty of Nursing and Midwifery
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Grant name
Guilan University of Medical Science
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Gilan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Azad University
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Leila Moghtader
Position
Assistant Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available